BioCLIA® Autoimmune Calibrator Set

β2 Glycoprotein 1 IgM

β2 Glycoprotein 1 IgM Assay Calibrators

Key to Symbols Used

REF	Catalog Number		Expiration Date
IVD	For *In Vitro* Diagnostic Use	LOT	Lot Number
	Store between +2°C and +8°C		Consult Instruction for Use
	Manufacturer	EC REP	Authorized Representative in European Union
		Σ	Contains Sufficient for < *n* > Tests
CAL 1	Calibrator 1		
CAL 2	Calibrator 2		Chemical Risk Warning
			Biological Risk Warning

BioCLIA® Autoimmune Calibrator Set, β2 Glycoprotein 1 IgM

Intended Use

The BioCLIA Autoimmune Calibrator Set, β2 Glycoprotein 1 IgM is intended for the calibration of the BioCLIA β2 Glycoprotein 1 IgM performed on the BioCLIA® 1200 and BioCLIA® 6500.

Catalog Numbers

MY00228 (2 X 1 mL)

MY00279 (4 X 1 mL)

Summary and Principles of the Procedure

β-2 glycoprotein I (or called apolipoprotein H) antigens are plasma proteins existing free or bound to low density lipoprotein. They act as an auxiliary factor for cardiolipin and anti-cardiolipin antibody combination. [1, 2] In autoimmune disease, anti-β-2 glycoprotein I antibodies, also called anti-apolipoprotein H (AAHA) antibodies, comprise a subset of anti-cardiolipin antibodies and lupus anticoagulant.

These antibodies are involved in sclerosis and are strongly associated with thrombotic forms of lupus, as a result they are strongly implicated in autoimmune deep vein thrombosis. [3] About 30-60% anti-phospholipid syndrome (APS) patients are anti-β-2 glycoprotein I antibodies positive. They are also closely associated with thrombosis. Determination of anti-β-2 glycoprotein I antibodies can significantly increase the prediction rate of thrombosis complications. [4] As these antibodies only appear in autoimmune disease patients, they are regarded as autoimmune thrombus markers to distinguish autoimmune diseases and infectious diseases. [5] Anti-β-2 glycoprotein I antibodies have a specificity of 98% while anti-cardiolipin antibodies (aCL) of 75% for APS diagnosis; however, the sensitivity is only 54% which is lower than the aCL. Besides, concentration of anti-β-2 glycoprotein I antibodies is related to the severity of thrombosis in systemic lupus erythematosus (SLE) patients. [6]

Materials supplied

- **β2 Glycoprotein 1 IgM Calibrator 1** A tube contains 1mL, ready to use reagent. Calibrator 1 contains human IgM antibodies to β2 Glycoprotein 1 in stabilizers and preservatives.

β2GP1-M	CAL	1

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **β2 Glycoprotein 1 IgM Calibrator 2** A tube contains 1mL, ready to use reagent. Calibrator 2 contains human IgM antibodies to β2 Glycoprotein 1 in stabilizers and preservatives.

β2GP1-M	CAL	2

Preservatives: 0.0015% < Proclin 300 < 0.6%.

Target value information is indicated in the 2D barcode localized in each kit.

Warnings and Precautions

The human derived material in this product was tested by FDA approved methods and found nonreactive for Hepatitis B Surface Antigen (HBsAg), Anti-HCV and HIV 1/2 antibodies. Handle as if potentially infectious. [7] Avoid contacting with skin and eyes. Do not empty into drains. Wear suitable protective clothing.

T Precautions:

 Human serum is added in the calibrators

 Proclin 300 is added in the calibrators at concentration between 0.0015% - 0.6%.

- The product is for *in vitro* diagnostic use only.
- Do not use any calibrators beyond their expiration dates. Do not mix calibrators from different lots unless specified.
- Instructions must be carefully followed for using and storing of calibrators. Any modification in procedure may interfere with the results. Calibrators and contaminated vials must be handled strictly following safety guidelines or rules of biological hazards to ensure the users' and environmental safety.
- Calibrators contain chemical and biological components. Avoid ingesting or splashing onto skin and mucous membrane. If direct contact with calibrators happens, rinse immediately the contact surface with plenty of water and see a doctor if necessary.

Storage Conditions

The kit is stable until the expiration date, if stored and handled as directed. Routine store the kit in refrigerator (2-8°C). Once a calibrator tube is opened, it is good for a total of 15 times, no more than 2 hours per time when kept uncapped, onboard the instrument, after which the reagent must be discarded. Three freeze-thaw cycles before testing has no effect on the kit reagents.

Assay Procedure

Note that, for obtaining optimal performance, it is important to perform all routine maintenance procedures as defined in the BioCLIA® 1200 and BioCLIA® 6500 User Manual.

See the BioCLIA® 1200 and BioCLIA® 6500 User Manual for preparation, setup, dilutions, adjustment, assay and quality control procedures.

Traceability

The reported values were determined over multiple runs on the BioCLIA® 1200 and BioCLIA® 6500 using specific lots of reagents against an in-house standard. β2 Glycoprotein 1 IgM results are

reported in RU/mL which is interpreted from relative light unit (RLU). Method comparison test showed good sensitivity and specificity of tested assay.

Limitations

This product is designed as calibrators for monitoring the performance of the BioCLIA β2 Glycoprotein 1 IgM. These calibrators are subjected to the limitations of the assay system. Deviations may indicate problems with one or more components in the test system.

References

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2. Schousboe I, Rasmussen M. Synchronized inhibition of the phospholipid mediated autoactivation of factor XII in plasma by beta 2-glycoprotein I and anti-beta 2-glycoprotein I. Thrombosis and haemostasis 1995;73:798-804.
3. Viard J, Amoura Z, Bach J. [Anti-beta 2 glycoprotein I antibodies in systemic lupus erythematosus: a marker of thrombosis associated with a circulating anticoagulant]. Comptes rendus de l'Academie des sciences. Serie III, Sciences de la vie 1990;313:607-12.
4. Galli M, Bevers E, Comfurius P, Barbui T, Zwaal R. Effect of antiphospholipid antibodies on procoagulant activity of activated platelets and platelet‐derived microvesicles. British journal of haematology 1993;83:466-72.
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6. Tsutsumi A, Matsuura E, Ichikawa K, Fujisaku A, Mukai M, Kobayashi S, Koike T. Antibodies to β 2‐glycoprotein I and clinical manifestations in patients with systemic lupus erythematosus. Arthritis & Rheumatism 1996;39:1466-74.
7. Richmond JY, Mckinney RW. Biosafety in microbiological and biomedical laboratories: U.S.GPO. 1999.

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EC REP

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Technical Assistance

For technical assistance, contact your National Distributor.

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